



05-29-07

IFU

CASE BP/G-32574A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
BETZ ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP03/07347

FILED: 8 JULY 2003

U.S. APPLICATION NO: 10/520,569

35 USC §371 DATE:

FOR: LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF  
HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

**MS: Amendment**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is supplemental to the Information Disclosure Statement filed January 7, 2005. Since Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, no fees are believed to be required under 37 C.F.R. §1.97(b)(3). If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark J. Bowditch', written over a horizontal line.

Mark Bowditch  
Attorney for Applicants  
Reg. No. 40,315

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(609) 627-8507

Date: 5/25/07

## INFORMATION DISCLOSURE CITATION

(Use separate sheets if necessary)

ATTY. DOCKET NO.  
BP/G-32574A  
APPLICATION NO.  
10/520,569  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,981,485	11/9/99	O'connor et, al			
	AB	4,637,834	1/20/87	Thurrow			
	AC	4,783,441	11/8/88	Thurrow			
	AD	5,374,620	12/20/94	Clark et, al			
	AE	5,597,802	1/28/97	Clark et, al			
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM	WO 2001/03741	1/18/01	Grandis Biotech GMBH			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 1993/19776	4/1/93	Pharmacia Artiebolar			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 1993/12811	12/16/92	Novo Nordisk			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 1993/19776	4/1/93	Kabi Pharmacia			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 1991/14454	4/2/91	Skua Investments Ltd			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Isosmotic and Isotonic Solutions
	AS	Jorgensen et al, "Patent Acceptance of Nordiject: A new drug delivery system for growth Hormone"
	AT	R. Pearlman & T. Bewley " Stability and Characterization of Human Growth Hormone"

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)



ATTY. DOCKET NO.  
BP/G-32574A  
APPLICATION NO.  
10/520,569  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group

EXAMINER  
INITIAL

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

	DA	Physicians Desk Reference - Pages 989-990
	DB	Journal of Parenteral Science and Technology, Technical Report 10
	DC	Physicians Desk Reference - Pages 1940 & 1941
	DD	K.H. Wellh����er "Pharma -Technik" pgs 716-722
	DE	S.P. Denyer et, al " Antimicrobial preservatives and their properties", pgs 252-272
	DF	Sean Evans and Peter Grassam " Considerations for Parenteral Dosage Form Development of Natural Alpha Interferon, pgs 83-87
	DG	Alfonso Gennaro, Remington Pharmaceutical Sciences , pages 1549-1550
	DH	
	DI	
	DJ	
	DK	
	DL	
	DM	
	DN	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)



ATTY. DOCKET NO.  
BP/G-32574A  
APPLICATION NO.  
10/520,569  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	CA	WO 1994/ 03198	7/29/93	Genentech, Inc			<input type="checkbox"/>	<input type="checkbox"/>
	CB	WO 1991/11200	1/25/91	Janssen Pharmaceutica			<input type="checkbox"/>	<input type="checkbox"/>
	CC	EP 0 938 902	9/1/99	JCR Pharmaceuticals Inc			<input type="checkbox"/>	<input type="checkbox"/>
	CD						<input type="checkbox"/>	<input type="checkbox"/>
	CE						<input type="checkbox"/>	<input type="checkbox"/>
	CF						<input type="checkbox"/>	<input type="checkbox"/>
	CG						<input type="checkbox"/>	<input type="checkbox"/>
	CH						<input type="checkbox"/>	<input type="checkbox"/>
	CI						<input type="checkbox"/>	<input type="checkbox"/>
	CJ						<input type="checkbox"/>	<input type="checkbox"/>
	CK						<input type="checkbox"/>	<input type="checkbox"/>
	CL						<input type="checkbox"/>	<input type="checkbox"/>
	CM						<input type="checkbox"/>	<input type="checkbox"/>
	CN						<input type="checkbox"/>	<input type="checkbox"/>
	CO						<input type="checkbox"/>	<input type="checkbox"/>
	CP						<input type="checkbox"/>	<input type="checkbox"/>
	CQ						<input type="checkbox"/>	<input type="checkbox"/>
	CR						<input type="checkbox"/>	<input type="checkbox"/>
	CS						<input type="checkbox"/>	<input type="checkbox"/>
	CT						<input type="checkbox"/>	<input type="checkbox"/>
	CU						<input type="checkbox"/>	<input type="checkbox"/>
	CV						<input type="checkbox"/>	<input type="checkbox"/>
	CW						<input type="checkbox"/>	<input type="checkbox"/>
	CX						<input type="checkbox"/>	<input type="checkbox"/>
	CY						<input type="checkbox"/>	<input type="checkbox"/>
	CZ						<input type="checkbox"/>	<input type="checkbox"/>

**EXAMINER**

**DATE CONSIDERED**

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.